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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/075,375	05/07/98	YAMAMOTO	H	CGNE119-2US

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EXAMINER
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/075,375	Applicant(s) Yamamoto et al.
	Examiner Ousama Zaghmout	Group Art Unit 1649

☒ Responsive to communication(s) filed on *09/075,375* .

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-15* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) *3* is/are allowed.

☒ Claim(s) *1, 2, and 4-15* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Serial Number: 09/075,375

Art Unit: 1649

Detailed Office Action

Claims 1-15 are pending.

Notice of draftsperson's patent drawing review (PTO 948) is enclosed.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

St. Paragraph

Claims 1-2, 4, 8-9 and dependent claims 6-7, 10-15 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The claims are generically drawn to any isolated DNA sequence that has at least 70% homology at the DNA level to the sequences shown in Fig.1 (SEQ ID:1) or Fig. 2 (SEQ ID:2) or Fig. 3 (SEQ ID:3). The specification fails to describe adequate representative species of the claimed nucleic acids by their relevant identifying characteristics, e.g. by sequence or other structure or properties. Only specific SEQ ID Nos: 1-6 are disclosed. At the time the application was filed, one of skill in the art could not have predicted the relevant identifying characteristics of the nucleic acids based only on the sequence of the corresponding gene. Accordingly, one of skill in the art would not have recognized the applicant to have been in possession of the claimed nucleic acids at the time the application was filed. Furthermore, there is no information in the literature or in the specification to predict if nucleotide sequences within this genus are very similar in structural and physical characteristics to define the claimed genus. In addition, it is not clear if these claimed but not disclosed nucleic acid molecules will be able provide a protein with biological activity and desirable traits when expressed in a cell. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. 35 USC 112 requires inter alia that a patent specification contain a written description of the invention and the manner and process of making and using it "in such full clear and concise terms as to enable one skilled in the art to make and use" the invention.

Case law has made it clear that the requirements for a "written description" and an "enabling disclosure" are separate. For example, where a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds but it makes no reference to the compound in question, the "written description" requirement has not been met even though the description may be enabling.

The separateness of the two requirements has been emphasized in the biotechnology area by two cases. Both cases involved interferences in which the count in question related to a strand of DNA. In one case Fiers v. Sugano [25 USPQ2d 1601 (Fed. Cir. 1993], :"An adequate description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself." In the Fiers case, convention priority was denied to a claim to a DNA sequence coding for a specified protein because of the absence of the actual sequence of the DNA in the priority documents. A similar situation occurred in Fiddes v.Baird [30 USPQ2d 1481 (Bd. of Appeals 1993).] where the Board of Appeals stated that "knowledge of amino acid sequence of a protein coupled with the established relationship in the genetic code between a nucleic acid and a protein it encodes would not establish possession of a gene encoding that protein."

Claims 1-2, 4-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabled for isolation of the nucleotide sequences that are disclosed in SEQ ID NOs: 1-6 and expression of the antisense construct of tobacco violaxanthin de-epoxidase (vde) in transgenic plants, does not reasonably provide enablement for isolation and expression of all vde genes nor for their overexpression in all transgenic plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The breadth of the claims are not commensurate in scope with the enabling support provided. Applicants broadly claim any isolated DNA sequence that has at least 70% homology at the DNA level to the sequences shown in Fig.1 (SEQ ID:1) or Fig. 2 (SEQ ID:2) or Fig. 3 (SEQ ID:3). Furthermore, Applicants claim any transgenic plant that express any plant vde encoding sequence. In addition, applicants claim any method for overexpressing and underexpressing any isolated vde sequence that causes modification in the sensitivity of the plant to light, increasing zeaxanthin level, increasing in the activity of vde, zeaxanthin, and antheraxanthin, and the time and the size of the flower. However, in the instant disclosure, applicants provide and explicitly demonstrate the production of transgenic tobacco plants that express only the cDNA sequence which encodes vde from tobacco under the transcription activities of CaMV 35S promoter. No other examples of nucleotide sequences of vde, other than of tobacco, Arabidospsis and lettuce, were disclosed in the instant disclosure. Applicants provide insufficient guidance as how to isolate, prepare, identify such materials other than a

general indication to go look for it. In addition, claiming a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features constitute a substantial portion of the genus. Furthermore, the mere germ of an idea does not constitute an enabling disclosure, and the specification, not the knowledge of one skilled in the art must supply the enabling aspects of the invention. See *Genentech, Inc. v. Novo Nordisk*, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997). Therefore, presentation of these examples by the applicants is very critical for the enablement of the claimed invention to show the physical components of the cDNA molecules and to further test them in transgenic plants to determine if a functional protein with full enzymatic activity where it will have the ability to provide claimed phenotypes resulting from the expression of the transgene of vde or any sequence that has at least 70% homology at the DNA level to the sequences shown in Fig.1 (SEQ ID:1) or Fig. 2 (SEQ ID:2) or Fig. 3 (SEQ ID:3). This is important in the light of the fact that the process of transforming plants with individual genes to obtain desired phenotypes is unpredictable. Napoli et al. observed a reversible inhibition of expression of the desired gene, when introduced in sense orientation into a plant, so that the desired phenotype was not observed (The Plant Cell. 1989. Vol. 2: 278-289. see page 279, Abstract).

Furthermore, it is not clear from the instant disclosure if transgenic plants that over express the tobacco vde is tolerant to increase in certain of stress factors such increased light levels. This is uncertain in the previous teaching which clearly indicates that transformation with genes which encode stress resistance related proteins will not necessarily produce

transgenic plants that are resistant to stress. This and other teachings of similar nature will undoubtedly render such process to be highly unpredictable. In that respect, Tepperman and Dunsmuir teach that transformed plants with elevated levels of chloroplastic SOD are not more resistant to superoxide toxicity (Plant Mol Biol 1990 April issue. Vol. 14: 501-511. See abstract). The petunia nuclear gene which encodes the chloroplast isozyme of superoxide dismutase, SOD-1, was fused with an efficient rbcS promoter fragment and 3' flanking region and introduced into tobacco and tomato cells. Transformed plants carrying this chimeric gene have up to 50-fold the levels of SOD-1 which occur in wild-type plants. However, tobacco plants with 30- to 50-fold the normal SOD-1 activity do not exhibit resistance to the light-activated herbicide paraquat. Similarly, tomato plants with 2- to 4-fold increases in SOD-1 do not exhibit tolerance to photoinhibitory conditions known to increase superoxide levels (high light, low temperatures and low CO2 concentrations). Our data indicate that increasing the chloroplastic SOD level in a plant cell is not sufficient to reduce the toxicity of superoxide (Abstract). Taken together, the instant disclosure lacks the proper and sufficient guidance to enable the claims as set forth. Thus it is not readily predictable that the genetic modification specifically disclosed will work with other claimed genes and in any plant species. Applicants have provided no specific guidance as to how to select genes which will give the desired effect or provided guidance with regard to selection of other plants and/or the technique to be used in the modification of these genetic modification of these plants. One wishing to practice the invention is left to proceed through trial-and-error to see what will work and what will not.

In view of the breadth of the claims, unpredictability, lack of guidance in the specification of the results as stated above, it is the examiner's position that one skilled in the art to which it pertains, or with which it is most nearly connected, could not practice the invention commensurate in scope with these claims without undue experimentations. See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

2nd Paragraph

Claims 1-2 and dependent claim 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-2 are objected to for their omission of a sequence identifier, as required by 37 CFR 1.821 (d).

Claims 1-2 and dependent claim 10 are rejected as being indefinite for the use of relative term "at least" which renders the claims indefinite and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This word not defined by the specification. The specification does not provide a standard for ascertaining the requisite

degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 1-2 and dependent claim 10 are confusing as it is unclear which sequence is claimed: the recitation of " 70% "homology" to any sequence of figure 1, 2 and 3. The use of the term "homology" to refer to a degree of sequence similarity is confusing, since this term is recognized in the art to refer to qualitative evolutionary relationships rather than quantitative measurements of sequence identity.

For more details on limitations following the phrase which are part of the claimed invention, see MPEP § 2173.05(d).

Conclusion

Claims 1-15 are deemed free of the prior art given the failure of the prior art to teach or suggest the particularly claimed DNA sequence and their usage in transformation experiments.

Claim 3 is allowed for the failure of the prior art to teach this particular nucleic acid molecule.

Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Ousama M-Faiz Zaghmout whose telephone number is (703) 308-9438. The Examiner can normally be reached Monday through Friday from 7:30 am to 5:00 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, L. Smith, can be reached on (703) 308-3909. The fax phone number for the group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to THE MATRIX CUSTOMER SERVICE CENTER whose telephone number is (703) 308-0196.

Ousama M-Faiz Zaghmout Ph.D.

January 5, 1999

GARY BENZION
PRIMARY EXAMINER